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10/724,520	11/26/2003	Yves Faisandier	8707.2170	8916

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EXAMINER

SUNDARARAMAN, VIKRAM P

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/724,520	Applicant(s) FAISANDIER, YVES	
	Examiner Vikram P. Sundararaman	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-9, 14-17, 19-20 is/are rejected.
- 7) ☒ Claim(s) 7, 10-13 and 18 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. **Claims 1-3, 8, and 14** are rejected under 35 U.S.C. 102(a) as being anticipated by Xu et al, US 6,368,283 B1, hereinafter referred to as Xu.

3. As to **Claim 1**, Xu teaches “a non-invasive method and apparatus for estimating the systolic and pulmonary artery pressures of a patient” [Column 3, Lines 66-67] (A device for the noninvasive measurement of a patient’s blood pressure) comprising:

“...a PCG (phonocardiograph)... an acoustic signal recorded non-invasively by an air-coupled or contact microphone or a vibration transducer... Referring to Figure (1), an electric signal representative of the heart sounds of a patient is produced via the air-coupled or contact microphone or vibration transducer (6). This signal is amplified via a dedicated amplifier (10) and digitized by the computer (12) producing a digitized electric signal $x_s(t)$ which is representative of the heart sounds of a patient.” [Column 6, Lines 15-17, 41-47]

Art Unit: 3736

"A first producing means is provided for producing an electrical signal $x_s(t)$ representative of the heart sounds of the patient. This first producing means is preferably embodied by the microphone (6) and the dedicated amplifier (10). Also included is a first extracting means for extracting the second heart sound $S_2(t)$ from the signal produced from the first producing means." [Column 6, Lines 55-61]

"... an estimating means for estimating the systolic and mean pulmonary artery pressures by means of predetermined regressive functions, said predetermined regressive functions describing relationships between the normalized splitting interval and the systolic and mean pulmonary artery pressures." [Column 7, Lines 16-22]

(at least one sensor to be placed on a thoracic wall of a patient, said sensor being responsive to acoustic signals generated by the closing of the patient's cardiac valves and transmitted through the thorax, and producing an electronic phonocardiographic signal corresponding to said detected acoustic signals; discriminating means for identifying and extracting from the phonocardiographic signal a vibratory profile related to a second cardiac noise periodically produced at the end of systole, and means for analyzing at least one predetermined parameter of the vibratory profile and, in response, delivering according to said at least one parameter, a phono-arterial index value representative of the patient's blood pressure)

Art Unit: 3736

4. As to **Claim 2**, Xu teaches that “preferably the first extracting means, the second extracting means, the third extracting means, the correlating means, the measuring means, the second producing means and the estimating means are embodied by the computer (12).” [Column 7, Lines 22-25] It is inherent that the computer has a memory and that the phonocardiograph signal must be stored/recorded at least while it is being processed.

5. As to **Claim 3 and Claim 14**, Xu teaches “a first determining means is implemented for filtering $W_s(t,f)$ obtained from the first determining means. This uses the following function to obtain a masked time-frequency representation $m_A(t,f)$ of the aortic component of $A_2(t)$: $m_A(t,f) = W_s(t,f) * \text{Mask}(t,f)$. The $\text{Mask}(t,f)$ is set to 1.0 around a first most dominant ridge, both in time and frequency, of $W_s(t,f)$, and 0.0 elsewhere.” (an extrema of the phonocardiographic signal for a duration of the vibratory profile or a surface of the phonocardiographic signal) [Column 7, Lines 55-65]. Xu also teaches that there exists “a retrospective study by Chen D. et al, ‘Estimation of pulmonary artery pressure by spectral analysis of the second heart sound,’ American Journal of Cardiology, vol. 78, pp. 785-789, 1996.” [Column 3, Lines, 41-44] According to the method described in the cited reference, “the spectra of S2, A2, and P2 were [then] computed by using a Hanning window and a zero-padded 1,024-point fast-Fourier transform.” (a derivative of the phonocardiophic signal) and “seven spectral features were extracted from these 3 spectra.” Furthermore, according to Figure 2 of the cited

Art Unit: 3736

reference, F_p , F_a , F_s , f_1 and f_2 may all be considered as variations of the derivative of the phonocardiographic signal.

6. As to **Claims 8 and 19**, Xu discloses "a filtering means for low-pass filtering the signal obtained" (means for low pass filtering the determined phono-arterial index) [Column 8, Lines 25-26].

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 4, 5, 15, and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu in view of Schulhauser et al, US 6,869,404 B2, hereinafter referred to as Schulhauser.

9. As to **Claim 4**, Xu discloses the claimed invention as described in Paragraphs 3-4 of this action except for wherein the analyzing means further comprises means for applying a weighted value to said at least one parameter, said weighted value being variable from one vibratory profile to another. Schulhauser teaches an apparatus and method of chronically monitoring heart sounds for deriving estimated blood pressure.

Art Unit: 3736

Schulhauser teaches that "based on the best fit analysis, a weighted predicted blood pressure value is determined for each spectral variable." Furthermore according to Equation (1) of Schulhauser, "wherein $WBP(P_i)$ is the weighted predicted blood pressure based on the i^{th} spectral variable, P_i ; TSW is the total significance weighting, for the linear regression analysis of all spectral variables, and a and c_i are the x coefficient and constant determined by the linear regression of P ." [Column 13, Lines 14-30] Schulhauser solves the same problem of Xu (estimating blood pressure using the second heart sound), and discloses a specific method of analysis towards estimating blood pressure based on the vibratory profile of the second heart sound. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to modify Xu to include an analysis as disclosed by Schulhauser for estimating blood pressure on the basis of the second heart sound of the heart.

10. **Claims 5, 15, and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu in view of Schulhauser as discussed above.

11. **Claims 6 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu in view of Mohler, US 6,050,950, hereinafter referred to as Mohler.

12. As to **Claim 6**, Xu discloses the claimed invention as described in Paragraphs 3-4 of this action except for wherein at least one said sensor further comprises at least a first sensor and a second sensor, and means for combining the phonocardiographic

Art Unit: 3736

signals delivered by the at least first and second sensors into a combined signal, wherein said phonocardiographic signal of said discriminating means comprises said combined signal. Mohler discloses a passive/non-invasive systemic and pulmonary blood pressure measurement apparatus, operation, and method which uses sensors to detect "patient physiological signals, such as acoustic vibrations or electrical impulses," [Column 7, Lines 7-9] in which the "sensor assembly, 102, can detect both physiologic and background signals." [Column 7, Lines 48-50] Furthermore, Mohler discloses an alternative embodiment wherein "one side of the sensor assembly, 102, comprises an audio transducer which is in contact with the skin while a second audio transducer on the opposite side faces away from the patient. This second transducer is designed to acquire ambient sounds in synchronism with the sounds reaching the transducer in contact with the patient's skin in order to reject common mode signals reaching both transducers. By adding the environmental signals out of phase the with the signals acquired from the patient, the sounds in common to both transducers are effectively cancelled." In this way Mohler uses a sensor, which is comprised of a first and second sensor by which the phonocardiographic signal is combined from. Therefore it would have been obvious to one with ordinary skill in the art at the time of the invention to modify Xu with the teaching of Mohler, as Mohler also solves the problem of acquiring acoustic signals from a patient to assess a physiological status of a patient.

13. As to **Claim 17**, are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu in view of Mohler as discussed above.

14. **Claim 9 and Claim 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu in view of Greenberger, US 5,492,129, hereinafter referred to as Greenberger. Xu discloses the claimed invention as described in Paragraphs 3, 4, and 6 of this action. What Xu lacks is a means for evaluating a respiratory frequency of said patient, wherein said means for low-pass filtering further comprising means for adaptive filtering at a variable cutoff frequency, and means for adjusting said variable cutoff frequency at the time of analysis. Greenberger discloses "a noise reducing stethoscope for placement on the body to detect internal body sounds" [Abstract]. Greenberger further teaches "a high pass filter can therefore be used effectively to separate the respiration sounds from the cardiac sounds... the cutoff frequency should be variable so that the user can trade off between the level of cardiac sounds heard and the amount of low frequency respiration sounds that are filtered out." [Column 7, Lines 65+ and Column 8, Lines 1-6] Since the apparatus of Greenberger is capable of solving the same problem of filtering respiratory noise during detection of internal body sounds, it would have been obvious to one with ordinary skill in the art at the time of the invention to modify the Xu to incorporate the variable cutoff filter of Greenberger. It is noted that while functionality of the variable cutoff filter can be used to perform the function of the means for evaluating the respiratory frequency, the means for adaptive filtering, and means for adjusting during the time of analysis, the applicant may overcome the rejection by including a limitation that the variable cutoff filter means is automatic.

Art Unit: 3736

Allowable Subject Matter

15. **Claims 7, 10-13, and 18** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

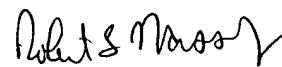
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vikram P. Sundararaman whose telephone number is 571.272.3351. The examiner can normally be reached on M-F, 730am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571.272.4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VPS


ROBERT L. NASSER
EXAMINER

Art Unit: 3736